

Male Urinary Pouch External Collection Device

General Information

The Male Urinary Pouch is a cut-to-fit, vinyl, self-adhering pouch, intended to be a conduit for urine collection, via tubing, into a gravity drainage collection device. The adhesive is synthetic. The pouch is meant to be worn by non-ambulatory men, and is available in two styles, either with the FlexTend™ or SoftFlex™ skin barrier. The male urinary pouch may be a good alternative when external catheters are not an option because of insufficient shaft length. Do not use this product if the penis or scrotal skin is compromised, if the tip of the penis retracts below the level of the scrotal skin, or if the patient is ambulatory.

FlexTend and SoftFlex Skin Barriers

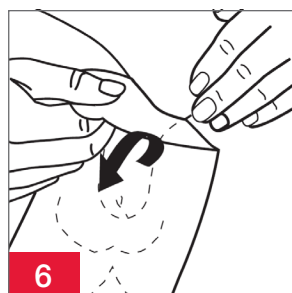
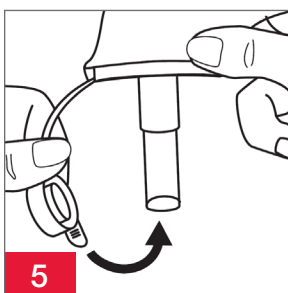
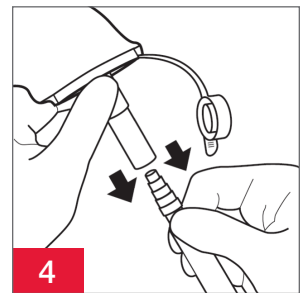
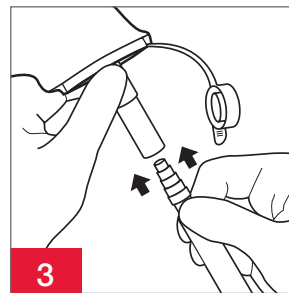
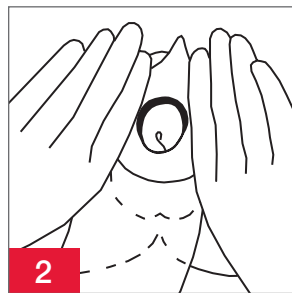
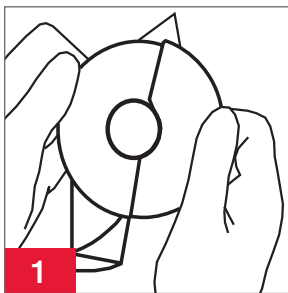
Selecting the Proper Size and Preparation

- Wash genital area with a mild soap and water.
- Trim the pubic hair. Rinse and dry thoroughly.
- Be sure the drain cap is placed on the pouch drain.
- If necessary, cut an opening in the skin barrier slightly larger than the penis.

Instructions for Use

1. Remove the protective release paper from the skin barrier
2. Place the penis in the opening of the pouch and press the barrier securely on skin. Avoid wrinkling, which can create channels for leakage. Gently hold the barrier material against the skin so that the user's body heat will soften the barrier material and enhance its adhesive properties.
3. Remove the drain cap at the bottom of the pouch and attach the tubing to a drainage bag (not included).

To dispose (Figs. 4-8): Please follow all local disposal regulations.



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FREQUENTLY ASKED QUESTIONS

If the penis is just about flush, how can the penis be centered in the pouch?	If the patient can be rolled slightly to the side, the shaft may lengthen itself enough for successful application.
What type of drainage bag should be used?	Select either a bedside drainage bag or larger capacity leg bag for the immobile individual.
Can the bedside drainage bag and leg bag be interchanged for day wear and night wear?	To minimize the risk of bacteria entering the tubing system, select just one type of collection bag and use it continuously.
How do I ensure gravity drainage into the collection bag?	A side-lying rather than supine position for the patient will help prevent urine from pooling around the penis as it sits in the opening of the pouch. Ensure that the tubing or end of the pouch is not twisted, and that the drainage bag is well below the bladder level. A catheter tubing securement device may also be used to help stabilize the tubing and prevent undue tension on the pouch.
When does the pouch need to be changed?	If the patient is not circumcised, the pouch should be removed for daily hygiene beneath the foreskin. Remove the pouch immediately if any skin irritation is assessed while the pouch is in place or if urine is undermining the skin barrier and urine leaks from beneath the barrier. The pouch should be changed when the inner pouch opening around the penis starts to “turtle neck” around the shaft. This is a sign that the barrier is absorbing maximum moisture and should be changed to prevent moisture accumulation between the barrier and scrotal skin.

Indications and Intended Use

This product is intended to collect and contain urine for individuals with urinary incontinence.

WARNINGS

Reuse of a single use product may create potential risk to the user such as poor adhesion. Reprocessing, cleaning, disinfection, and sterilization may compromise the product. This may result in odor or leakage.

Precautions

Discontinue use of this product if any of the following signs or symptoms occur:

- Changes in the skin color of the penis
- Extreme skin temperature changes
- Swelling, burning, itching, pain or loss of sensation

Notes

To help ensure proper adhesion, apply to clean, dry intact skin. Do not use oils or lotions. These products may interfere with adhesion of the skin barrier. Frequent removal of a FlexTend skin barrier in a short period of time (e.g., multiple times a day) may result in skin damage. Contact a healthcare practitioner for help with continence care products.

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